DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION

Complete and Return Only the Original Form to: Food and Drug Administration Center for Devices & Radiological Health, HFZ- 308

Form Approved: OMB No. 0910-0387 Expiration Date: April 30, 2008

1. TODAY'S DATE (mm/dd/yyyy)

DEVICE LISTING

9200 Corporate Blvd., Rockville, MD 20850-4015

NOTE: This form is authorized by Section 510 of the Federal Food, Drug, and Cosmetic Act (21 LLS C 360). Failure to report this information is a violation of Section 301(n) of the Act (21 LLS C 331(n)). Persons who violate this

r, and a person is not required to respon	id to a collection of information unless it	respect is a violation of Section 301(q))(2), (21 U.S.C. 331(q)(2)) and may be ⊓number.
	4. REGISTRATION NUMBER		
2	5. ESTABLISHMENT NAME (Business name)		
MDIE	NUMBER AND STREET		
ZIP CODE	СІТУ	STATE	ZIP CODE
COUNTRY	FOREIGN STATE	POSTAL CODE	COUNTRY
6. LISTING INFORMATION: Number of product codes you are going to list for this establishment:			
ready Listed Delete Listing	REASON FOR LISTING: Nev	Listing Update to Device A	Already Listed Delete Listing
510(k) NUMBER	PRODUCT CODE	PMA NUMBER	510(k) NUMBER
CLASSIFICATION NAME			
	PROPRIETARY NAME		
	COMMON OR USUAL NAME		
3	PREVIOUS LISTING NUMBER LISTING NUMBER		
_		H 1, 11	essor of Single-use device
			cation Developer anufacturer of Export Only Devices
REASON FOR LISTING: New Listing Update to Device Already Listed Delete Listing REASON FOR LISTING: New Listing Update to Device Already Listed Delete Listing			
510(k) NUMBER	PRODUCT CODE	PMA NUMBER	510(k) NUMBER
	CLASSIFICATION NAME		
	PROPRIETARY NAME		
	COMMON OR USUAL NAME		
٦	PREVIOUS LISTING NUMBER LISTING NUMBER		
ssor of Single Use Devices		Manufacturer Reproce	essor of Single Use Devices
· ·	Contract Sterilizer Remanufacturer Specification Developer Foreign Exporter Repackager/Relabeler U.S. Manufacturer of Export Only Devices		
TYPED OR PRINTED NAME	TITLE		
	ZIP CODE COUNTRY or this establishment: ready Listed Delete Listing 510(k) NUMBER Second Single Use Devices ation Developer nufacturer of Export Only Devices ready Listed Delete Listing 510(k) NUMBER	4. REGISTRATION NUMBER 7. ESTABLISHMENT NAME (Busine) NUMBER AND STREET NUMBER AND STREET NUMBER AND STREET NEW FOREIGN STATE OR THIS establishment: REASON FOR LISTING: New PRODUCT CODE CLASSIFICATION NAME PROPRIETARY NAME COMMON OR USUAL NAME PREVIOUS LISTING NUMBER REASON FOR LISTING: New PROPRIETARY NAME COMMON OR USUAL NAME PREVIOUS LISTING NUMBER REASON FOR LISTING: New PRODUCT CODE CLASSIFICATION NAME CONTRACT Sterilizer PROPRIETARY NAME CLASSIFICATION NAME PROPRIETARY NAME CLASSIFICATION NAME PROPRIETARY NAME COMMON OR USUAL NAME PREVIOUS LISTING NUMBER REASON FOR LISTING NUMBER COMMON OR USUAL NAME COMMON OR USUAL NAME PREVIOUS LISTING NUMBER COMMON OR USUAL NAME COMMON OR USUAL NAME	5. ESTABLISHMENT NAME (Business name) NUMBER AND STREET COUNTRY FOREIGN STATE POSTAL CODE On this establishment: PREASON FOR LISTING: New Listing PRODUCT CODE PMA NUMBER COMMON OR USUAL NAME PREVIOUS LISTING NUMBER LISTING NUMBER REASON FOR LISTING: PROPRIETARY NAME COMMON OR USUAL NAME PREVIOUS LISTING NUMBER LISTING NUMBER REASON FOR LISTING: PREVIOUS LISTING NUMBER LISTING NUMBER REASON FOR LISTING: PREVIOUS LISTING NUMBER LISTING NUMBER REASON FOR LISTING: PROPOUCT CODE PMA NUMBER Update to Device A PROPOUCT CODE PMA NUMBER CLASSIFICATION NAME PROPORTIETARY NAME CLASSIFICATION NAME PROPRIETARY NAME CLASSIFICATION NAME PROPRIETARY NAME COMMON OR USUAL NAME PROPRIETARY NAME COMMON OR USUAL NAME PREVIOUS LISTING NUMBER LISTING NUMBER LISTING NUMBER LISTING NUMBER COMMON OR USUAL NAME PROPRIETARY NAME COMMON OR USUAL NAME PREVIOUS LISTING NUMBER LISTING NUMBER LISTING NUMBER REPROCUES LISTING NUMBER LISTING NUMBER LISTING NUMBER REPROCUES LISTING NUMBER LISTING NUMBER REPROCUES LISTING NUMBER LISTING NUMBER LISTING NUMBER LISTING NUMBER REPROCUES LISTING NUMBER LISTING NUMBER LISTING NUMBER LISTING NUMBER REPROCUES LISTING NUMBER LISTING NUMBE